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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/075,970 | 02/14/2002 | Michael Helmus | 01-202 | 9278 |
| 27774 | 7590 | 06/28/2005 | EXAMINER | |
| MAYER, FORTKORT & WILLIAMS, PC 251 NORTH AVENUE WEST 2ND FLOOR WESTFIELD, NJ 07090 | | | HO, UYEN T | |
| | | ART UNIT | PAPER NUMBER | |
| | | 3731 | | |

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|-------------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/075,970 | HELMUS, MICHAEL |
| | Examiner (Jackie) Tan-Uyen T. Ho | Art Unit 3731 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 01 April 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-45 is/are pending in the application.
 4a) Of the above claim(s) 3,4,9,10 and 22-45 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,2,5-8 and 11-21 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____

5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

Election/Restrictions

1. Applicant's election with traverse of Species I in the reply filed on 4/1/05 is acknowledged. The traversal is on the ground(s) that "it is not believed that a species election is proper under the present circumstances and that species elections are applicable where a generic claim to a generic invention is present. This is not found persuasive because there are two distinct species as indicated in the previous office action and should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant indicates claims 1-21 and 45 readable thereon (species I). Examiner disagrees. Species I: with biodegradable inner material and biodegradable outer/covering material (claim 1, 2, 5-8, 11-21). Claims 3, 4, 9, 10 and 45 direct to hydrogel, metallic and ceramic inner material, which are disclosed in the specification as a non-biodegradable material. Note: The specification (paragraph 39) discloses the hydrogel as claimed in claim 45 being the outer coating material. There is no suggestion for these materials to be used as the inner material as claimed in claim 1.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-19 and 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Paragraphs 40-43 of the specification disclose non-biodegradable materials such as hydrogels, ceramic, metallic for inner material/core. Claim 1 cited a biodegradable inner material being ceramic, metallic which were not described in the specification in such a way as to enable one skilled in the art to which it pertains or to make or used the invention.

4. Claims 1-19, 45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a biodegradable inner material being erodable polymer or biodegradable polymers, does not reasonably provide enablement for a biodegradable inner material being metallic, ceramic. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Paragraphs 40-43 of the specification disclose non-biodegradable materials such as hydrogels, ceramic, metallic for inner material/core.

Since the specification does not support the subject matter as claimed, art rejection below is made according to the examiner's best interpretation of the claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 5-8, 11-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Datta et al. (6,338,739). Datta et al. disclose a biodegradable stent comprising a biodegradable inner core which become softened/flexible filament when contact with body fluids (col. 17, lines 40-64) and a biodegradable outer layer and the stent coated with therapeutic agent (col. 12, lines 8-60), the inner core can be made more than one filaments and from woven cloth, mesh or flat stock that is rolled into shape (col. 8, lines 38-47).

7. Claims 1, 5-8, 11-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Wang et al. (WO98/56312). Wang et al. disclose a stent a biodegradable stent comprising a biodegradable inner core and a biodegradable outer layer and the stent coated with therapeutic agent, the stent can be made as self-expanding, woven or mesh like structure (page 2, lines 19-32)

Art Unit: 3731

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731

June 13, 2005